An alternative approach for treatment of infantile esotropia with botulinum toxin A.

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24276

Source
Nationaal Trial Register

Health condition

Infantile esotropia.

Sponsors and support

Primary sponsor: The Rotterdam Eye Hospital (REH)
PO Box 70030
NL-3000 LM Rotterdam
tel: 010 4017777
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek het Oogziekenhuis Prof. Dr. H.J. Flieringa

Intervention

Outcome measures

Primary outcome

Proportion of successful motor alignment at six months. This will be measured with a synoptophore. Successful alignment is defined as ¡Ü ¡À10 prism diopters of residual esotropia

at 6 months.

Secondary outcome

1. Degree of esotropia (prism diopters);

2. Time of onset esotropia;

3. Measurement of binocularity: alignment & fusion;

4. Percentages and duration of ptosis and exotropia (temporary side effects of botulinum injection);

5. Percentages of reinjection and additional alignment surgery;

6. BCVA at each visit and amblyopia;

7. Occurrence of vertical disturbances of ocular motility;

8. Adverse events.

Study description

Background summary

Rationale:

In comparison to standard strabism surgery in patients with infantile esotropia, bilateral injection of Botox in the medial rectus muscle is conjectured to be equivalent with respect to motor alignment, while burden and risk are (because less invasive) expected to be less.

Objective:

To determine the proportion of successful alignment after treatment of infantile esotropia with Botox.

Study design:

Prospective case series.

Study population:

Infantile esotropia < 6 years of age.

Intervention:

Bilateral injection of Botox in the medial rectus muscle.

Main study parameters/endpoints:

Proportion of successful motor alignment at six months.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

As an alternative to conventional strabism surgery, treatment with Botox may be equally effective while both burden and risk are anticipated to be reduced.

Study objective

The proportion of successful alignment after treatment of infantile esotropia with Botox is not inferior to conventional strabism surgery.

Study design

Preoperatively, postoperatively at 2 and 10 weeks, at 6 months and at 1 and 2 years.

Intervention

Bilateral injection of Botox in the medial rectus muscle.

Contacts

Public
Rotterdam Ophthalmic Institute
Postbus 70030
Rene Wubbels
Rotterdam 3000 LM

The Netherlands
+31 (0)10 4023449
Scientific
Rotterdam Ophthalmic Institute
Postbus 70030
Rene Wubbels
Rotterdam 3000 LM
The Netherlands
+31 (0)10 4023449

Eligibility criteria

Inclusion criteria

1. No known/established neurological disease;

2. History of orthotropia;

3. No vertical deviation (no upshoots);

4. Non-accommodative (less than 3D spherical equivalent hyperopia);

5. Up to 40 Δ esotropia;

6. Free alternators;

7. Difference in refraction between both eyes ¡Ü 1.5 D.

Exclusion criteria

1. Previous strabismus surgery;

2. Retinal disease;

3. Any medical condition that would preclude general anesthesia with sevoflurane;

4. Hypersensitivity to any Botox ingredient;

5. Muscular disease such as myasthenia gravis or Eaton-Lambert syndrome.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-06-2013
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-04-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39876
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3764
NTR-old	NTR3959
CCMO	NL42631.078.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39876

Study results

Summary results
N/A